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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,803	01/12/2002	Philip Connolly	7287	3678

7590

03/19/2003

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EXAMINER

HENDRICKS, KEITH D

ART UNIT

PAPER NUMBER

1761

3

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,803

Applicant(s)

CONNOLLY, PHILIP

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: This application is a CIP of 09/517,502, and the current claims contain several of the same issues addressed in the parent application. *Applicants' representative is strongly encouraged to review the application, especially the claims, to comply with accepted U.S. Patent structure and language. The claims are generally narrative and indefinite, failing to conform with current U.S. practice, and are replete with grammatical and idiomatic errors. The rejections under 35 USC 112 2nd paragraph below are an attempt to call attention to these occurrences, yet may not be comprehensive.*

The term "enhancing", in at least claims 1 and 7 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Similarly, in claim 10, the terms "increasing", "harmful", "large", "more" and "efficiently", are indefinite, for the reasons stated immediately above.

Similarly, in claim 11, the term "improved" is indefinite, for the reasons stated immediately above.

Claim 5 is dependent upon itself. Thus, the metes and bounds of the claimed invention are unclear.

Claims 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The amount of protein administered in the claims is dependent upon the amount of "total daily consumption of protein by the subject", as well as the amount of protein contained in the "combination of milk protein concentrates and probiotic bacteria." None of the three amounts are provided, yet in order for one skilled in the art to determine the metes and bounds of the claimed invention, all three must be known. Even if a total

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amount of protein were provided in the claims regarding that contributed by the milk concentrates and the bacteria, this still would not provide how much is to be "administered" (which is what is actually claimed) as a percentage of the "total daily consumption of protein by the subject", since the total daily consumption is variable and indeterminable from the claims.

Claims 11 and 15 are indefinite due to the recitation of the phrase "containing *Bifido* bacteria and lactic acid bacteria". *Bifido* bacteria are lactic acid bacteria, and thus the metes and bounds of the claimed invention are unclear. It is unclear if the limitations of the claims would be satisfied by (a) two of the same *Bifido* bacteria, (b) two different species of *Bifido* bacteria, or only by (c) a *Bifido* bacteria and another non-*Bifido* bacteria genus/species of lactic acid bacteria.

In claim 13, the phrase "... into a tank to produce hydrolyzed milk peptones" is indefinite. The claim is disjointed and confusing, as it is unclear as to what tank the starter culture is introduced, and what this tank holds, such that hydrolyzed milk peptones may somehow be produced. Further in claim 13, the phrase "which are combined with hydrolyzed milk peptones" is disjointed and confusing, as the correlation to the rest of the claim, as well as to claim 11 from which it depends, is unclear. It is unclear as to how the probiotic starter culture may be introduced into the tank to produce the hydrolyzed milk peptones, and yet the probiotic starter culture is also fed a base medium which comprises (the?) hydrolyzed milk peptones. It is suggested that the source/type of hydrolyzed milk peptones be recited.

The percentages "about 65% to about 90%" as recited in claim 15 appear to conflict with the same recited percentage values in the other claims. The corresponding phrases of each of the percentages within these claims are not necessarily equivalent, and thus the claims are unclear, and indefinite with respect to the metes and bounds of the invention, also in view of the teachings of the specification. In claim 15, the step of "combining a powder form of skim milk protein content having a skim milk protein content of about 65% to about 90%" as a starting component with powdered microorganisms, is not the same as the recitation in claim 4 or 17, for example, where the entire concentrate appears to contain the milk protein as well as liquid to bring the protein total to about 65% to 90% by weight. The percentage of protein contained in a powder product would not be expected to be the same as that contained in a total liquid and protein product. There does not appear to be support in the specification for each different recitation of the same percentages.

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In claim 17, it is unclear as to the distinction between *Lactobacillus acidophilus* and some other "Acidophilus bacteria". Further, it appears that the claim includes Acidophilus bacteria in both parts (B) and (C), and thus the metes and bounds of the claimed invention are unclear.

In the phrase "milk having a milk protein concentrate of 65% to 90%" in claim 17, it is unclear as to how milk, a natural product, may have "a milk protein concentrate of 65% to 90%".

The use of the percentages "0.1% to 1%" in claims 17 and 18, is indefinite, as it is unclear as to what whole entity these percentages pertain. To contrast, the percentage "65% to 90%" appears to pertain to the milk protein within the milk ingredient; however, the percentages of the bacteria are unclear, in relation to the whole (0.1% to 1% of what?). Further, this is disjointed from the recitation of the number of microorganisms per gram of milk protein concentrate, as it is unclear as to how one skilled in the art is to determine the amount of microorganisms to utilize in the product. It is also unclear if the number of microorganisms ("100,000 to 50,000,000") refers to each type of microorganism recited in parts (A), (B) and (C), or if this is a total of all three, or some other total number.

The term "thoroughly" in the penultimate line of claim 17 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 17, part (C), the phrase "chosen from the group consisting essentially of" is indefinite, and is not considered acceptable Patent terminology. The phrase "chosen from the group consisting of" is acceptable, and is considered a closed set. Thus, the metes and bounds of the phrase utilizing the term "essentially", are unclear, and do not sufficiently and properly define the claimed invention. This is further complicated by the use of the terms "including" and "chosen from the group consisting essentially of", in an attempt to define the invention. Applicant is encouraged to maintain consistent phrasing throughout the claims, especially regarding the terms "including", and "comprising". It is suggested that the term "comprising" be used throughout, instead of "including", as "comprising" has judicially-based definition in the Patent system.

Claim 17, part (C), appears to be missing essential text. Part (C) appears to begin a list of components, which only begin with (c), thus missing at least (a) and (b). The claim will be examined against the prior art to the best extent possible, however, this is made difficult by the state of the claim.

The last two lines of claim 17 appear to be misplaced, and are disjointed from the product of the claim. This does not appear to be a method claim, nor a product-by-process claim, yet the last two lines recite process steps involving "mixing".

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In claim 18, the phrase "may be added" is indefinite, as the claim lacks guidance or means to tell whether this applies to the weight percentage of the bacteria (i.e. they "may be added" in this amount), or if this applies to the actual bacteria listed. Further, as this is a dependent claim, the term "may be" is not necessary, as claim 5 already "includes" ("comprises" is the preferred Patent term) these possibilities, and thus dependent claim 18 should serve to *positively* define a desired limitation. It is suggested to be amended to recite "are added". Finally, the dependency of product claim 18 appears incorrect, as claim 5 is directed to a method. It appears that claim 18 was simply copied from claim 6 in the parent application (which depended from claim 5 in that application, mirrored by claim 17 in this application), yet the dependency was not changed.

Claim Objections

Claims 1-18 are objected to because of the following informalities. Appropriate correction is required.

- The term "Bifidio" should be "*Bifido*" (spelling and italics).
- In each claim reciting the microorganism name of "*bifidus longum*", this should be amended to "*Bifidobacterium longum*". No organism named "*bifidus longum*" appears to exist.
- The scientific names of the microorganisms should be capitalized for the first letter of the genus, while small letters for the species that follows. For example, "*lactobacillus helveticus*" should be "*Lactobacillus helveticus*". It is also suggested that the claims maintain consistency throughout, with italics and capitalization. See claim 18.
- In claim 15, line 4, the term "with" improperly appears twice consecutively.
- In claim 7, line 2, the phrase "comprising the oral administration of" improperly appears twice consecutively.
- In the last line of claim 15, the term "comined" should be "combined".
- Claim 18 should be kept consistent with the other claims, with regard to the types of microorganisms. Compare "Bifido Bacteria" in claims 17 to "Bifidobacterium" in claim 18.
- In claim 15, and in part (C) of claim 17, it is suggested that the phrase "Lactic Acid Producing Bacteria" be amended to "lactic acid-producing bacteria", with a hyphen, and where the letters are not capitalized (unnecessary).

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Note:** As the instant claims are indefinite and/or incomplete (see for example, product/process claim 17), for the reasons set forth in the above pages, examination against the prior art proved difficult. The following rejections are applied as they best appear suitable to the instant claimed invention.

1) Claims 1-18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meister et al.

Meister et al. disclose a process for producing a "dehydrated food composition containing live probiotic lactic acid bacteria." Basically, the reference utilizes concentrated skim milk and cultures of various probiotic lactic acid bacteria (see especially column 2), to co-spray the two components to form a combined powder containing the two. The referenced product pertains to a milk protein concentrate and "a culture of one or more species of probiotic lactic acid bacteria" (col. 2, ln 50-51), where the recited bacteria include *Bifidobacterium longum*, *Streptococcus thermophilus*, and *Lactobacillus delbrueckii subsp. bulgaricus*, also known simply as *Lactobacillus bulgaricus*. Thus, there does not appear to be any distinction between the prior art and applicant's invention.

Regarding the second two steps of instant claim 11 ("filtering" and "discontinuing"), these are simply techniques for forming concentrated milk, and the last step of "inoculating" is simply a known culturing technique to create the lactic acid bacteria cultures. These do not appear to contribute an inventive step to the claims, *per se*. Regarding the steps of inoculating the filtered/concentrated skim milk with the bacteria, these steps were known and taught by the reference as well. Meister et al. utilizes

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a concentrated skim milk, and the step of filtering the skim milk was a well known and art-recognized technique for forming said concentrated milk. This known step of forming the known product does not appear to be the crux of applicant's invention, and does not appear to contribute an inventive step to the claims.

Further, note that the CFU/g from Table 1 of the reference are within the claimed approximate ranges. Further, the product of instant claims 17-18 is also anticipated by the reference; note that the product is neither powdered nor dried.

Alternatively, the percentages of concentration and/or drying and filtering of the starting milk product, as well as the microorganism counts, would have been well within the ordinary level of skill in the art to have produced, based upon the positive teachings of the reference with regard to culture conditions, desired amounts effective in the final product, and the judicious selection of one of ordinary skill in the art. Thus, one of ordinary skill in the art, based upon the teachings of the reference and the state of the art at the time the invention was made, would have been motivated to have produced the claimed invention.

ii) Claims 1-2, 4-7 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bohren.

Bohren discloses a method and product similar to Meister et al. above, regarding a lactic-acid bacteria-containing powdered milk product. Bohren specifically disclose the use of *Streptococcus thermophilus* and *Lactobacillus bulgaricus*.

Alternatively, the percentages of concentration and/or drying and filtering of the starting milk product, as well as the microorganism counts, would have been well within the ordinary level of skill in the art to have produced, based upon the positive teachings of the reference with regard to culture conditions, desired amounts effective in the final product, and the judicious selection of one of ordinary skill in the art. Thus, one of ordinary skill in the art, based upon the teachings of the reference and the state of the art at the time the invention was made, would have been motivated to have produced the claimed invention.

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iii) Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of the following: Kronberg, Jameson et al., Nielsen, or Kosikowski et al.

Kronberg discloses a method and product similar to Meister et al. above, regarding a lactic-acid bacteria-containing powdered milk product.

Jameson et al., Nielsen, and Kosikowski et al. are concerned with processes and products for fermented milk concentrates, whether eventually used in cheese or other food products.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



**KEITH HENDRICKS
PRIMARY EXAMINER**